

### THE OFFICE ACTION

Claims 153-158 were rejected as being unpatentable over Sauer et al. (U.S. Patent No. 5,176,836) or Frommer et al. (U.S. Patent No. 5,110,479) each taken alone or in view of Rosenblatt (U.S. Patent No. 5,071,648).

### REMARKS

The claims, 153 to 158, have been rejected under 35 U.S.C. § 103 as being unpatentable over Sauer, et al. (U.S. 5,176,836) or Frommer, et al. (U.S. 5,110,479) taken alone or in view of Rosenblatt (U.S. 5,071,648). The Applicant submits that these claims are patentably distinct from the cited references.

Claims 153 to 158 relate to a method for disinfecting a biological or body fluid by contact (i.e. use) with a disinfectant resin. The disinfectant resin may be:

- i) a demand disinfectant resin, in particular an iodinated strong base anion exchange resin (claim 156);
- ii) a demand disinfectant iodinated strong base anion exchange resin having a strong base anion exchange resin component which represents from 25 to 90 percent by weight of the total weight of the iodinated resin (claim 157);
- iii) a demand disinfectant iodinated strong base anion exchange resin having a strong base anion exchange resin component which represents from 45 to 65 percent by weight of the total weight of the iodinated resin (claim 158);
- iv) an iodinated insoluble anion-exchange matrix material to which is complexed greater than 20% to about 70% iodine (by weight) (claim 153)
- v) an iodinated insoluble anion-exchange matrix material iodinated to a concentration of greater than 20 % to about 60 % iodine (by weight) (claim 154); and
- vi) an iodinated insoluble anion-exchange matrix material iodinated to a concentration of greater than 25 % to about 50 % iodine (by weight) (claim 155).

Before turning specifically to the obviousness rejections in the Office Action, we would like to make the following general comments:

- a) The Applicant submits that the present application's claims were copied from U.S. Patent No. 6,096,216 to Shanbrom et al. Two of the references cited in the present Office Action (U.S. Patent No. 5,176,836 to Sauer et al. and to U.S. Patent No. 5,071,648 to Rosenblatt) were considered during the prosecution of Shanbrom et al. Applicant would like to point out that in accordance with MPEP § 2307.02, if a ground of rejection in an application which has claims copied from a patent is applicable to the patented claims as well, any letter including the rejection must have the approval of the Technical Center Director. See also MPEP § 1003. In the present application no Director approval is noted for the rejection under 35 U.S.C. § 103(a) of the claims copied from U.S. Patent No. 6,096,216.
- b) The Applicant submits that in order to justify a rejection on obviousness, the references relied upon should contain a teaching which provides a specific suggestion or motivation for the exploitation of the subject matter of a claim.
- c) The Applicant submits that the examiner must consider the teachings of each of the prior art documents taken **as a whole** in order to determine what each document teaches i.e. whether or not the cited art suggests the subject matter of the present application.
- d) In any event, the Applicant notes that nowhere has the Examiner indicated where in either of the primary references (Sauer et al. or Frommer et al.) or in the secondary reference (i.e. the Rosenblatt reference (U.S. 5,071,648) can there be found a specific suggestion for the subject matter of the claims, namely the disinfection of body fluids.
- e) Moreover, the general invention or concept of the present application resides in the **idea** or appreciation that an "iodinated (anion exchange)

resin" may be used as a (demand) disinfectant resin for the disinfection of a body fluid.

As mentioned above, the Applicant believes that the Examiner should consider the teachings of each of the prior art documents taken **as a whole** in order to determine whether or not the cited art suggests the "method" of the present application.

The examiner indicates that in light of the cited references "It is known in the art to treat **fluids** with iodine/exchange resins ....." (emphasis added) . The Applicant submits that in light of the cited references, it is only known to treat **water** to obtain potable water. Applicants submit that the limited teaching of disinfecting water with iodine is clearly not predictive of disinfecting bodily fluids with iodinated (strong base) anion exchange resins.

The primary Sauer et al ('836) and Frommer et al ('479) references each deal solely with the use of disinfection materials to disinfect water so as to obtain a "potable water supply". These references do not suggest to use iodinated (strong base) anion exchange resins to disinfect body fluid.

Apparently recognizing the deficiencies of Sauer et al. and Frommer et al, the Examiner cites Rosenblatt. The secondary reference, namely the Rosenblatt ('648) reference, does not provide any suggestion that iodinated (strong base) anion exchange resins may be used to disinfect body fluids. Thus, Rosenblatt, as in the case of the prior mentioned two references (Sauer et al. and Frommer et al.), does not deal with the problem of how to disinfect body fluids and thus does not teach nor suggest that disinfectant iodinated resins may be used to disinfect body fluids.

Additionally, the Applicant submits that there is no suggestion in either of the primary references or in the secondary reference to use iodinated resins, having the iodine content as specified in claims 153, 154, 155, 157 and 158, for disinfection of body fluid. Applicant notes that claims 153, 154, 155, 157, and 158 all recite specific iodine content for the disinfecting resins which are not disclosed by the cited references.

If the Examiner is relying on an obviousness type rejection, the Examiner must comply with the requirements for establishing obviousness as set

forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), which are summarized as follows:

(A) the relevant teachings of the prior art relied upon, preferably with each reference to the relevant column or page number(s) and line number(s) where appropriate,

(B) the difference or differences in the claim over the applied reference(s),

(C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and

(D) an explanation why one of ordinary skill in the art at the invention was made would have been motivated to make the proposed modification.

The Examiner is also pointed to the MPEP at section 706.02(j) which recites the steps of *Graham* and summarizes as follows:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teachings or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not in the Applicant's disclosure. *In re Vaech*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991).

In order for an invention to be obvious over a prior art reference, it has been held that the prior art reference itself must suggest the desirability for the modification to be considered an obvious prior art reference. *In re Fritch*, 922 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed.Cir. 1992).

In the present application, there is simply no motivation or suggestion to a person of ordinary skill in the art to disinfect a biological or body fluid with an iodinated strong base anion exchange resin. As such, Applicant submits that the rejection is improper and must be withdrawn.

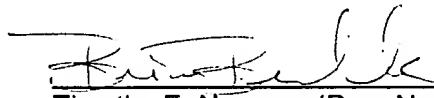
### **CONCLUSION**

Applicant believes that this response fully addresses all issues raised by the Examiner in the Official Action. Applicant believes that the claims are in condition for allowability. Applicant respectfully requests notification of allowability and that the application be forwarded to the appropriate party for determination of the interference issue. The Examiner is encouraged to contact the undersigned should any issues remain.

Respectfully submitted,

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